7/17/00 JEW

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M39821

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-65

July 10, 2000

Charles Barwick, Owner
Barwick Crab Company
38 Barber Road
Crawfordville, Florida 32326

Dear Mr. Barwick:

We inspected your crabmeat processing plant on May 5, 2000 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your ready-to-eat crabmeat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find the Act and these regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for refrigerated pasteurized crabmeat received and stored by your firm to control the potential food safety hazard of pathogens.

You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for cooked ready-to-eat crabmeat does not list a critical limit for time at the cooking critical control point to control the potential food safety hazard of pathogens. This deviation was previously brought to your attention in our letter of August 26, 1998.

You must have monitoring records which document the actual values and observations obtained during monitoring, in order to comply with 21 CFR 123.6(c)(7). However, you did not have the monitoring records specified in your HACCP plan for cooked ready-to-eat crabmeat to document cumulative time at the picking/boning/packing critical control point to control the potential food safety hazard of pathogens. This deviation was previously brought to your attention in our letter of August 26, 1998.

> You must have sanitation control records that document monitoring and corrections of sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(c). However, your sanitation control records are not being completed at the time the operation is being performed. The records are being checked with an erasable marker pen on a marker board and the information is being transferred later onto permanent records.

In addition, the investigator also observed numerous insanitary conditions and practices during the inspection that are conducive to microbiological contamination of your cooked ready-to-eat crabmeat, for example, poor employee practices, transportation carts that were not washed or sanitized used to store perforated baskets of both cooked and raw crabs, equipment encrusted with residues from previous operations and poor clean up practices. We consider these observations to be serious food GMP deficiencies (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your cooked ready-to-eat crabmeat and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plan for refrigerated pasteurized crabmeat, your revised HACCP plan for cooked ready-to-eat crabmeat, monitoring records, sanitation control records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice (CGMP) regulations for foods (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

Emma R. Singleton
Director, Florida District